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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,940	11/21/2001	Hui Tian	018781-007410US	2892

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EXAMINER
KAUFMAN, CLAIRE M

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 07/01/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/990,940	TIAN ET AL.	
	Examiner	Art Unit	
	Claire M. Kaufman	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-48* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The preliminary amendment filed 2/27/02 has been entered.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I-III. Claims 1-9, drawn to nucleic acid related to SEQ ID NO:7, 9 or 11, respectively, classified in class 536, subclass 23.1.

IV-VI. Claims 10-13, drawn to polypeptide related to SEQ ID NO:8, 10 or 12, respectively, classified in class 530, subclass 350.

VII-IX. Claim 14, drawn to antibody that binds SEQ ID NO:8, 10 or 12, respectively, classified in class 530, subclass 387.1.

X-XI. Claims 17-25, 31 and 32, drawn to nucleic acid related to SEQ ID NO:15 or 17, respectively, classified in class 536, subclass 23.1.

XII-XIII. Claims 26-29, drawn to polypeptide related to SEQ ID NO:16 or 18, respectively, classified in class 530, subclass 350.

XIV-XV. Claim 30, drawn to antibody that binds SEQ ID NO:16 or 18, respectively, classified in class 530, subclass 387.1.

XVI-XXII. Claims 33-41, drawn to method of identifying a modulator of a polypeptide related to SEQ ID NO: 2, 4, 6, 8, 10, 16 or 18, respectively, classified for example in class 435, subclass 7.1.

XXIII-XXIX. Claims 42-43, drawn to a method of detecting a TGR nucleic acid related to SEQ ID NO: 1, 3, 5, 7, 9, 15 or 17, respectively, classified in class 435, subclass 6.

XXX-XXXVI. Claims 44-45, drawn to method of identifying a TGR- associated disorder by detecting a TGR polypeptide related to SEQ ID NO: 2, 4, 6, 8, 10, 16 or 18, respectively, classified for example in class 436, subclass 503.

XXXVII-XLIII. Claims 46-48, drawn to method of treating or preventing a disorder using a modulator of a polypeptide related to SEQ ID NO: 2, 4, 6, 8, 10, 16 or 18, respectively, classified for example in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Each of SEQ ID NOS: 2, 6, 8, 10, 16 and 18, inconjunction with their respective encoding nucleic acids of SEQ ID NO: 1, 3, 5, 7, 9, 15 or 17, are unrelated on to another because while they share some sequence similiarity, each is a distinct sequence with each different polypeptide being encoded by a different nucleic acid. SEQ ID NO:1 and 2 correspond to TGR342. SEQ ID NO:5 and 6 correspond to human TGR346. SEQ ID NO: 7 and 8 and then 9 and 10 correspond to two distinct splice variants of human TGR60 which are expressed as two different protein sequences. SEQ ID NO: 15 and 16 and then 17 and 18 correspond to mouse TGR346a and b, respectively, which have different sequences and expression (see Figs. 10A and 10B). For these reasons, each of the above sequence pairs is an independent and distinct invention. Additionally, the burden of search for the Office has increased with multiple sequences because of the rapid introduction of new sequences to public sequence databases.

The nucleic acids of Inventions I-III and X-XI are related to the proteins of Invention IV-VI and XII-XIII by virtue of encoding the same. The nucleic acids have utility for the recombinant production of the protein in a host cell. Although the nucleic acids and proteins are related since the nucleic acids encode their specifically claimed respectively proteins, they are distinct inventions because the protein products can be made by another and materially different process, such as by synthesis or purification from the natural source. Further, the nucleic acids may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

Inventions I-III and X-XI are unrelated to VII-IX and XIV-XV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not used together and have different effects.

Inventions I-III and X-XI are unrelated to XVI-XXII and XXX-XLIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not used together as the methods do not use nucleic acids and they have different effects.

Inventions I-III and X-XI are related as product and process of use to Inventions XXIII-XXIX. The inventions can be shown to be distinct if either or both of the following can be

shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used for a materially different process such as in the production of the encoded protein or in library screening for species homologues.

The proteins of Invention IV-VI and XII-XIII are related to the antibodies of Invention VII-IX and XIV-XV by virtue of being the cognate antigen, necessary for the production of the antibody. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because the protein can be used for another and materially different process other than for production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein (as the protein is asserted to be itself a receptor), or in assays for the identification of agonist or antagonists of the receptor protein.

Inventions IV-VI and XII-XIII are unrelated to XXIII-XXIX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not used together as the methods do not use protein but require the nucleic acid and they have different effects.

Inventions IV-VI and XII-XIII are related as product and process of use to Inventions XVI-XXII and XXX-XLIII. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used for a materially different process such as in the production of an antibody.

Inventions VII-IX and XIV-XV are unrelated to XVI-XLIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not used together as the methods do not use antibody but require instead the nucleic acid or encoded protein and they have different effects.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, have recognized divergent subject matter, and because each invention requires a separate non-coextensive search, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: method of treating retinitis pigmentosa, method of regulating circadian rhythms, both with modulator of TGR60 (SEQ ID NO:8 and 10, which are themselves distinct and constitute different inventions).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 46 of Inventions XL and XLI are generic. Therefore, if either Invention XL or XL1 is chosen, a species election must follow.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Thursday from 8:30AM to 12:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (703) 308-6564.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.

Claire M. Kaufman, Ph.D.

Claire M. Kaufman

Patent Examiner, Art Unit 1646

June 26, 2003